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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,188	01/12/2004	Brian P. Brockway	22570-032001	2296

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EXAMINER	
SCHAETZLE, KENNEDY	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
06/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/756,188	BROCKWAY ET AL.	
	Examiner	Art Unit	
	Kennedy J. Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 19, 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheldon et al. (Pat. No. 6,937,899) in view of Brockway et al. (Pat. No. 4,846,191).

Sheldon et al. disclose a method of internally monitoring a subject and providing, if appropriate, cardiac electrical therapy to the subject, the method comprising:

implanting within the subject a cardiac defibrillator comprising a pulse generator, processing circuitry, and electrodes that are positioned to sense cardiac electrical waveforms and to provide, if needed, cardiac therapy in a form of electrical defibrillation stimulation (see Fig. 1 and col. 4, lines 25-56);

implanting within the subject a pressure sensing device (see for example col. 2, lines 13-65);

receiving, within the implanted cardiac defibrillator, cardiac electrical activity waveform information sensed by the electrodes and pressure waveform information for the artery sensed by the implanted pressure sensor (e.g., see col. 4, lines 30-33 and lines 57-64); and

providing the cardiac therapy in the form of electrical defibrillation stimulation if the processing circuitry of the implanted cardiac therapeutic device determines that an evaluation of both the cardiac electrical activity waveform information and the pressure waveform information shows there is occurring an aberrant rhythm for which therapy is appropriate (see col. 4, lines 25-47).

Sheldon et al. do not discuss particulars associated with the detection of vascular blood pressure. Brockway et al., however, disclose such details with an implantable sensor that can be used in any situation requiring an accurate, long-term measure of blood pressure and/or accurate control of therapeutical devices (note col. 3, lines 27-36, col. 4, lines 28-38). The method of Sheldon et al. requires exactly such a sensor since it is required to provide accurate, reliable, feedback data of vascular blood pressure for controlling therapy application in a chronically implanted system. Those of ordinary skill in the art given the sensor requirements set forth by Sheldon et al. and the advantages of a candidate sensor meeting the requirements as disclosed by Brockway et al., would have clearly seen the obviousness of employing the sensor of Brockway et al. into the system and method of Sheldon et al.. It should also be noted that, as shown in Fig. 1, the sensor of Brockway et al. is positioned so that a distal sensing tip of the pressure transmission catheter is positioned within an artery but the transducer of the pressure sensing device remains outside of the artery.

Regarding claim 33, although Brockway et al. disclose a wireless connection between the transducer and processing circuitry, the use of a wired connection and concomitant connector structure would have been considered a matter of obvious design dependent upon the desired location of the pressure sensor in relation to the cardiac defibrillator housing, and such factors as ease of implant and system cost. One would expect a wired connection to work equally as well as a wireless connection since both connections serve the same function of transmitting information from one point to another and both have found common usage in the medical arts. In the very least,

substituting a wired connection for a wireless connection would have been considered obvious to try given that both are well known solutions to transmitting information and both yield predictable results with a reasonable expectation of success.

Regarding claim 38, while the exact location of placement for the pressure sensor discussed by Sheldon et al. is not disclosed, Sheldon et al. teach that any number of suitable locations may be chosen including locations within the heart, within the vasculature, or even around a blood vessel (see col. 2, lines 43-46). Clearly Sheldon et al. do not desire to limit the implant of the pressure sensor to any one particular location. Those of ordinary skill in the art would have considered the exact placement to be a matter of obvious design dependent upon the particular individual under treatment. One would have expected any location suitable to detect a pressure change resultant from ischemia to be suitable to the Sheldon et al. invention. The subclavian artery is a well-known artery useful because it is easy to access and may be used to place defibrillation and pacing leads within the heart. Given the known use of the artery in defibrillation and pacing applications and given the general suggestion by Sheldon et al. that the sensor can be placed within the vasculature, those of ordinary skill in the art would have considered the use of the subclavian artery to be a matter of obvious design, and in the very least, obvious to try placement of the sensor in this location.

Regarding claim 39, the examiner considers Sheldon et al. to inherently use a "likelihood function" to indicate the likelihood of a stimulus requiring aberrant rhythm because if both the electrical and mechanical activity of the heart indicate an aberrant

rhythm, then it is more likely than not that the patient is experiencing a cardiac condition warranting therapy.

Regarding claim 40, note col. 2, lines 28-37. The detection of noise in an implantable medical device to increase sensing accuracy and prevent unnecessary therapy would have been considered a matter of obvious design by those of ordinary skill in the art looking to increase the accuracy and reliability of electrical ECG signal interpretation. Common sense and prudence dictates that if a signal is noisy and difficult to interpret, then the chances that the signal can accurately detect situations requiring therapy would be unlikely. One would expect a noisy signal to be unreliable in properly diagnosing patient condition.

Regarding claim 41, while Sheldon et al. do not discuss the detection of a fall in pressure in order to indicate the presence of an aberrant rhythm, since ischemia reduces the heart's pumping capacity and efficiency, one would expect to see an abnormal fall in pressure. Those of ordinary skill in the art looking to detect ischemic conditions via pressure would have therefore seen the obviousness of detecting a fall in pressure from a baseline value of more than a pre-specified (i.e., normal) value.

Related comments to those made above in the rejection of claims 30-41 apply to substantially similar apparatus claims 42-52. It should further be noted that the particular location of apparatus fails to distinguish to prior art that recites the claimed structure as long as the prior art structure is at least capable of such placement.

Response to Arguments

5. Applicant's arguments filed May 19, 2008 have been fully considered but they are not persuasive.

In response to applicants' arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding the argument that sensors of the type disclosed by the Brockway patent have been around for many years yet "...no one has recognized how they may be used advantageously and beneficially as described and claimed in the present application," contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

Regarding the applicants' argument that there is no suggestion in the Brockway patent for using the sensor in therapeutic applications, Sheldon et al. suggest the use of pressure sensors in their therapeutic system. One of ordinary skill in the art would reasonably expect any implantable pressure sensor capable of use in human applications to be suitable to the Sheldon et al. invention. It is unclear why the pressure signal developed by the Brockway '191 invention would be any less useful in a therapy situation.

Conclusion

6. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy J. Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766

KJS
June 21, 2008